

K092782

## ATTACHMENT 5

DEC - 7 2009

## 510(K) SUMMARY

### Summary of Safety and Effectiveness

In accordance with 21 CFR 807.92, the following information constitutes the Carmel Pharma ab summary for the Injector N30, N31, N34, N35 and N35C and Connector C35, C40 and C45 included in:

**PhaSeal® - A Closed System Drug Transfer Device for Preparation and Administration of Parenteral Drugs**

SUBMITTER'S NAME: Carmel Pharma ab  
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CONTACT PERSON: Kjell Andreasson  
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DATE OF SUBMISSION: September 4, 2009

#### 1. Identification of device

Proprietary Name: PhaSeal Injector and Connector  
Common Name: I.V. Fluid Transfer Set  
Classification Status: Class II per 21 CFR 880.5440  
Product code: LHI.

#### 2. Equivalent devices

Injector N30 and N31 and Connector C40 cleared in K972527 and K001368.

#### 3. Description of the Device

The Injector and Connector is a sterile device for single-use within the PhaSeal® closed system drug transfer device for preparation and administration of parenteral drugs.

#### 4. Indication for use

The intended use of the Injectors is to inject fluids into, and to withdraw fluids from a drug vial, and then to inject fluids into a primary or secondary IV administration set, or into an IV container.

The Connector is a connector between the PhaSeal Injector and parts of an IV administration set up such as a stopcock or an admixture channel of the spike for the IV container. The PhaSeal elastomeric membrane seals with the elastomeric membranes of other PhaSeal components to help prevent drug spillage.

## 5. Technological characteristics, comparison to predicate device.

### *Injector Luer N34*

Subject	N34	Predicate N30, K972527	Equiv.
Intended use	The intended use of the Injectors is to inject fluids into, and to withdraw fluids from a drug vial, and then to inject fluids into a primary or secondary IV administration set, or into an IV container.	The intended use of the Injectors is to inject fluids into, and to withdraw fluids from a drug vial, and then to inject fluids into a primary or secondary IV administration set, or into an IV container.	Yes
Cannula	Stainless steel – pencil point cannula	Stainless steel – cut cannula	Yes
Needle safety lock	Safety sleeve “ErgoMotion™”	Safety latch	Yes
Fitting connection	Luer – rotation	Luer – no rotation	Yes
Sterilization method	EtO	EtO	Yes

### *Injector Luer Lock N35 and N35C (including a cap)*

Subject	Modified N35 and N35C	Predicate N31, K001368	Equiv.
Intended use	The intended use of the Injectors is to inject fluids into, and to withdraw fluids from a drug vial, and then to inject fluids into a primary or secondary IV administration set, or into an IV container.	The intended use of the Injectors is to inject fluids into, and to withdraw fluids from a drug vial, and then to inject fluids into a primary or secondary IV administration set, or into an IV container.	Yes
Cannula	Stainless steel – pencil point cannula	Stainless steel – cut cannula	Yes
Needle safety lock	Safety sleeve “ErgoMotion™”	Safety latch	Yes
Fitting connection	Luer Lock – rotation	Luer Lock – no rotation	Yes
Sterilization method	EtO	EtO	Yes

**Connector Luer Lock C35**

Subject	Connector C35	Predicate C40_K972527	Equiv.
<b>Intended use</b>	This device is a connector between the PhaSeal Injector and parts of an IV administration set up such as a stopcock or an admixture channel of the spike for the IV container. The PhaSeal elastomeric membrane seals with the elastomeric membranes of other PhaSeal components to help prevent drug spillage.	This device is a connector between the PhaSeal Injector and parts of an IV administration set up such as a stopcock or an admixture channel of the spike for the IV container. The PhaSeal elastomeric membrane seals with the elastomeric membranes of other PhaSeal components to help prevent drug spillage	Yes
<b>Bayonet fitting</b>	reduced notches – no click	notches – with a “click”	Yes
<b>Length</b>	26 mm	26 mm	Yes
<b>Sterilization method</b>	EtO	EtO	Yes

**Connector Luer Lock C45**

Subject	Connector C45	Predicate C40_K972527	Equiv.
<b>Intended use</b>	This device is a connector between the PhaSeal Injector and parts of an IV administration set up such as a stopcock or an admixture channel of the spike for the IV container. The PhaSeal elastomeric membrane seals with the elastomeric membranes of other PhaSeal components to help prevent drug spillage.	This device is a connector between the PhaSeal Injector and parts of an IV administration set up such as a stopcock or an admixture channel of the spike for the IV container. The PhaSeal elastomeric membrane seals with the elastomeric membranes of other PhaSeal components to help prevent drug spillage	Yes
<b>Bayonet fitting</b>	reduced notches – no click	notches – with a “click”	Yes
<b>Length</b>	34 mm to provide for CLAVE connection	26 mm	Yes
<b>Sterilization method</b>	EtO	EtO	Yes

**6. Discussion of performance testing.**

The Injectors and Connectors have been tested and found in compliance with applicable requirements and standards specifications.

**7. Conclusion**

Based on comparison to the predicate device, we come to the conclusion that the Injectors N34, N35, N35C and Connectors C35, C45 included in the PhaSeal System, are substantially equivalent to previously cleared predicate devices and present no new concerns about safety and effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
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Mr. Kjell Andreasson  
President Quality Assurance and Regulatory Affairs  
Carmel Pharma AB  
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SE 431 53 Molndal  
SWEDEN

DEC - 7 2009

Re: K092782

Trade/Device Name: Injector Luer N34  
Injector Luer Lock N35  
Injector Luer Lock N35C  
Connector Luer Lock C35  
Connector Luer Lock C45

Regulation Number: 21 CFR 880.5440

Regulation Name: Intravascular Administration Set

Regulatory Class: II

Product Code: LHI

Dated: September 4, 2009

Received: September 10, 2009

Dear Mr. Andreasson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature consisting of a stylized 'S' followed by the word 'For'.

Susan Runner, D.D.S., M.A.  
Acting Division Director  
Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

# Attachment 1

## Indications for Use Statement

510(k)  
Number  
(if known)

Device Name      Injector Luer N34  
                      Injector Luer Lock N35  
                      Injector Luer Lock N35C  
                      Connector Luer Lock C35  
                      Connector Luer Lock C45

Indications for Use      The indication for use of the PhaSeal system and included components are reconstitution and transfer of drug solutions from one container to another while minimizing exposure to potentially hazardous drugs aerosols and spills that can occur during the reconstitution, administration and disposal process.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: Yes  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use: No

  
(Division Sign-Off)  
Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number: K493732